2-25-93

IRB BRANCH REVIEW - TSS

Record Number(s)

D186032

IN 12/23/92 OUT 2/25/93

EFFICACY

FILE OR REG. NO. 64439-R

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 11/12/92?

DATE OF SUBMISSION ?

DATE SUBMISSION ACCEPTED 12/23/93

TYPE PRODUCTS(S): I, D, H, F, N, R, S

DATA ACCESSION NO(S). 425489-01?

PRODUCT MGR. NO. 14

PRODUCT NAME(S) MOLE-MED MOLE REPELLENT AND LAWN PROTECTION

COMPANY NAME Mole-Med

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 66% Oil of Ricinus, [redacted]

liquid concentrate

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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Efficacy Review: MOLE MED MOLE REPELLENT AND LAWN PROTECTION,
64439-R
Mole-Med
Aurora, IN 47001

200.0 INTRODUCTION

INERT INGREDIENT INFORMATION IS NOT INCLUDED

200.1 Uses

A 66% Oil of Ricinus and [redacted] liquid mixture proposed for registration as a "REPELLANT" to be used "to rid your yard of moles."

200.2 Background Information

See efficacy reviews of 6/19/90 and 4/30/91, other information in product's jacket, and information in brown folder prepared by Daniel B. Peacock to track legal actions pertaining to this product.

The initial submission pertaining to federal registration of this product apparently followed legal action in Indiana regarding sale of this product as an unregistered pesticide. Illegal sale has been alleged in several other states. Invoices collected to support such charges suggest that tens of thousands of product containers were involved. A penalty of $39,300 against the applicant is being sought.

Parties promoting this product have made various claims which, if made on pesticide labeling, would render the product misbranded. These include claims of absolute effectiveness and various safety claims. Mole-Med's ads also have quoted the Bible and have claimed that a

> "Mr. J. North, Raleigh, N.C. . . . felt like he had a rock in his stomach due to his yard being demolished by moles. He tried everything but nothing worked until he used MOLE-MED."

Mole-Med offered discounts on units of product to merchants who provided evidence that they had run at least one of three suggested ads in local newspapers.

In apparent endeavors to hasten the registration of this product (and perhaps to lessen the extent of EPA's scrutiny), Mole-Med has enlisted the support of U.S. Senators and a Congressman from Indiana, a law firm from Covington, KY, and Reed Environmental Services, also from Covington. Among the many items currently under review for MOLE-MED are requests for data waivers and speed in issuing registration.

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The material routed for my review consists of a narrative account of an efficacy study and three partially completed forms which present information pertaining to reported tests of the product.

201.0 DATA SUMMARY

The three efficacy report forms have been filled out partially by typing and partially in ink. The signature blocks for these forms are blank. These forms are identical to those discussed in the efficacy review of 4/30/91, except that the forms discussed in the earlier review all were signed by Eldon Pickett, the individual who appears to be in charge of Mole-Med. I concluded in the efficacy review of 4/30/91 that the completed forms were inadequate to support the claims made for the product.

The narrative report is authored by Uta Crisafulli and appears on stationery with the heading "Tsugawa," which refers to a facility located in Woodland, WA. Crisafulli is identified as a

"Bachelor of Science
Environmental Studies
College of Natural Resources
Utah State University"

Crisafulli's report consists of 27 lines of narrative text in which it is stated that two adjacent 20'-X-20' plots were demarcated with one being slated for treatment and the other left untreated. The treated area was said to include lawn, plantings of pansies and chrysanthemums, and a Japanese maple tree. The untreated side was "all lawn."

The product reportedly was diluted at a rate of one ounce of Mole-Med per gallon of water. Two ounces of product (and presumably two gallons of mixture) were used to treat the 400 square-foot area. After treatment, this area "was hosed down again for 20 minutes." Presumably just before or after treatment,

> ". . . all of the existing mounds were stomped down in both the treated and control areas."

Two days after treatment, there were reported to be eight new mounds in the untreated (and unwatered?) side but no new mounds in the treated side. A "custom constructed subterranean mole trap" reportedly was set in the untreated side and caught two moles. They were identified as Townsend's moles.

On February 24, 1993, I telephoned Tsugawa (which turns out to be a nursery and greenhouse operation) in an attempt to ascertain whether Uta Crisafulli still worked there. I was able to speak to Ms. Crisafulli. She said that the trial was run a year or so ago and was performed by a Tsugawa employee named Deborah Anderson who had had a problem with moles in her own yard. Ms. Anderson, who left Tsugawa about six months ago, reportedly had no training as a scientist.

Ms. Crisafulli said that she was asked to sign the report because Mr. Pickett wanted someone who had at least a B.S. degree to author the study. Ms. Crisafulli added that Pickett told Tsugawa personnel that the report only would be used in advertising to promote sale of the product and, therefore, that she was suprised to learn that the document had been submitted to EPA to support claims made for the product.

Ms. Crisafulli said that users of MOLE-MED have reported that mole activity stops in areas treated with it but not in areas immediately adjacent to it. Such a result was reported for the test claimed to have been run by Ms. Anderson.

I learned enough from Ms. Crisafulli to create grave doubts about the scientific integrity of the report which bears her name. In my opinion, the question of whether this product works remains unanswered. There certainly is enough evidence in the history of this product to call into question any representations made by Mr. Pickett.

The idea that castor oil could work as an area repellent for moles has some inherent "hokeyness," in as much as there is little positive evidence for any materials claimed to keep vertebrates out of areas and Pickett has been promoting MOLE-MED as an "Old Time Formula" that has worked "for years." On the other hand, it is possible that this product, made from castor oil and Dove soap, does repel moles from treated areas. Moles feeding in treated areas might ingest enough castor oil through direct contact with treated soil, or through indirect contact with tainted prey, to make the moles sick and, therefore, to develop a conditioned aversion to the flavor of the product. What we need to settle this issue is a good quality study conducted by a competent (and disinterested) scientist.

Many approaches to ridding areas of moles have been tried or suggested over the years. My personal favorite is the use of JUICY FRUIT chewing gum which moles are said to be able to ingest but not get rid of. Proponents of this approach say that the gum absolutely must be JUICY FRUIT. In a chapter on controlling moles in the vertebrate pest control manual Prevention and Control of Wildlife Damage (1983 edition, R.

M. Timm, ed., pp. D-60 to D-61), F. Robert Henderson offers the following comments on various old-time mole remedies, including castor beans:

> "Nearly everyone has heard of a surefire home remedy for controlling animals, especially moles. In this category are the many and varied materials recommended for placement within the burrow system. In theory such things cause the mole to die or at least pack up and leave. Such cures suggest placing broken bottles, ground glass, razor blades, thorny rose branches, bleaches, various petroleum products, sheep dip, household lye, and even human hair. Others include mole wheels, pop bottles, wind mills, bleach bottles with wind vents placed on sticks, and other similar gadgets. Though colorful and sometimes decorative, these add nothing to our arsenal of effective mole control methods.
>
> Other cure-alls are the so-called "mole plant" or caper spurge (Euphorbia lathris) and the castor bean. Advertisers claim that when planted frequently throughout the lawn and flower beds, such plants supposedly act as living mole repellents. No known research supports this claim. . . . Unfortunately, there are no "short cuts" no "magic wands" when controlling moles."

The efficacy review of 4/30/91 included comments on labeling submitted in November of 1990. Although I was not asked to comment on labeling in this review, it bears mentioning that a label evidently revised subsequent to 4/30/91 appears in the jacket for MOLE-MED and that copies of very old (and very bad) MOLE-MED labels seem to resurface from time to time.

A label which probably was submitted with the letter of 12/18/91 from Mole-Med's lawyer was revised with some attention having been paid to the labeling comments in efficacy review of 4/30/91. Under "CONCLUSIONS," I offer comments on this revised proposed label.

The "instant misbranding" statements (e.g., "ENVIRONMENTALLY SAFE," "contains no harmful chemicals," and "NOT HARMFUL TO ANIMALS, BIRDS OR PLANTS") that appeared in the labels discussed in the efficacy review of 6/19/90 have been dropped from the revised proposed label. These sorts of claims have appeared on Mole-Med's flyers and order forms in the past and, without a strict and specific directive prohibiting such practices, likely would be used in the future if the product were to be registered (or to be marketed illegally again).

202.0 CONCLUSIONS

1. The efficacy reports submitted for review included three form reports which we had reviewed earlier and found to be of inadequate quality to be used to support the claims made for this the product.

   The report from the Tsugawa nursery and greenhouse operation in Woodland, WA, for which Uta Crisafulli is listed as the author also is of questionable scientific integrity and is insufficient to support the claims for the product. As was noted in earlier correspondence, to be acceptable, a study must be designed as a controlled experiment which isolates the effects of your product from other factors which might affect mole activity in treated areas. Such a study must include monitoring of mole activity before and after the time of application in treated areas and in similarly infested untreated areas nearby. Conduct of such research also must conform to EPA's "GOOD LABORATORY PRACTICE STANDARDS" (40 CFR, Part 160). To claim more than one species (or to claim control of "moles" in general), trials must be run with types of moles which represent major eastern and western types. We suggest testing the eastern mole (Scalopus aquaticus) and any of the major Scapanus types which occur in the western U.S.

   Once again, we suggest that you contact biological or agricultural science departments of universities in Indiana and nearby states (e.g, Indiana State University, Purdue University, Michigan State University, Bowling Green State University, etc.) to find qualified individuals who might be interested in running field trials for you at reasonable costs. You might also wish to consult private laboratories. Before running such studies, you should submit a protocol describing the planned research. If this protocol requires 10 or more acres of land to be treated, you will be required to obtain an Experimental Use Permit (see 40 CFR, Part 172). If your consultant wishes to discuss the protocol while it is under development, he or she may contact Dr. William W. Jacobs of my staff at 703-305-6406.

2. The "DIRECTIONS FOR USE" portion of the proposed label submitted on December 18, 1991, must be restructured somewhat so that "DIRECTIONS FOR USE" is centered in the column in which it appears, with the "It is a violation . . . labeling" statement being left-justified and appearing directly below "DIRECTIONS FOR USE." The subheading "USE RESTRICTIONS" must be left-justified. A subheading entitled "MIXING DIRECTIONS" also is needed.

The amended "DIRECTIONS FOR USE" should appear as indicated below.

"DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: For repelling eastern moles and Townsend's moles from lawns.

MIXING DIRECTIONS: Mix with water at a rate of one ounce of MOLE-MED per gallon of water. Use the DILUTION TABLE below to determine the amount of mixture to prepare for the area that you intend to treat. SHAKE MOLE-MED CONTAINER WELL BEFORE MIXING.

DILUTION TABLE

Amount of MOLE-MED	Amount of Water	Area to be Covered
1 Oz.	1 Gal.	312 sq. ft.
2 Oz.	2 Gal.	624 sq. ft.
16 Oz.	16 Gal.	5,000 sq. ft.
32 Oz.	32 Gal.	10,000 sq. ft.

LOCATING MOLES: The presence of moles may be indicated by a network of surface ridges in the turf or by a series of conical mounds of earth pushed up from deep burrows. Treated all areas which show signs of moles' presence.

APPLICATION DIRECTIONS: Apply MOLE-MED with a hand-held sprayer or sprinkling can to entire area that is to be rid of moles or protected from moles. Cover treated area thoroughly with mixture of MOLE-MED and water. After treatment, water treated area with hose or sprinkler for an additional 25 minutes. If soil is dry, water area thoroughly prior to treatment. If heavy rains occur shortly after treatment, application may have to be repeated.

3. Labels proposed for this product in the past have included claims of absolute effectiveness and statements to the effect that the product is "safe" or somehow

ecologically appropriate. Such statements render pesticide products "misbranded" when they appear on labeling or any printed matter which accompanies the product in commerce. Such statement should not be used in any product advertising either.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
February 25, 1993

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